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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,433	01/23/2006	Ming Li	14184.0005USWO	1876
23552 7590 01/29/2007 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903			EXAMINER MCCORMICK, MELENIE LEE	
			ART UNIT	PAPER NUMBER
			1655	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/29/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/538,433	Applicant(s) LI ET AL.	
	Examiner Melenie McCormick	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>06/2005</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-20 are presented for examination on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8, 10, 12, and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 8 and 20, which is dependent therefrom, is rendered vague and indefinite by the phrase "10% by weight methanol" in line 2. It is not clear if the methanol is 10% by weight of the equilibrated column, or if a solution having a concentration of 10% by weight of methanol is used to equilibrate the column.

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The language of claim 10 renders the claim as a whole vague and indefinite. For example, the phrase "contains mainly tannins" in lines 1-2 is indefinite. It is not clear what value "mainly" represents. The claim is further considered to be indefinite because it is not clear if all of the tannins and triterpenes listed in the claim are necessarily required or if these tannins and triterpenes are examples, but are not all necessarily present within the extract.

Claims 12 provides for the use of an extract of *Geum Japonicum* thunb, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-7, 9-11, and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Xu et al. (US 5,916,919).

A method for preparing an organic extract from *Geum Japonicum* Thunb is claimed.

Xu et al. teach a method of extracting *Geum Japonicum* Thunb with methanol (a C1-C4 alcohol, as instantly claimed) at room temperature. Xu et al. further teach that the methanol extract obtained is evaporated in vacuo (under reduced pressure), which would inherently result in a dried powder (see e.g. col 8, lines 52-55). Xu et al. further disclose that the methanol extract was then successively extracted with hexane (C6 alkane), EtOAc and butanol (a C1-C4 alcohol). It is further disclosed by Xu et al. that the extract is then evaporated (dried) under reduced pressure (see e.g. col 8, lines 55-60). Xu et al. further teach that the dried extract is then applied to a chromatographic column and eluted with a linear gradient (increasing concentration) of a methanolic solution (see e.g. col 8, lines 61-64). Thus, the method taught by Xu et al. results in an extract of *Geum Japonicum* Thunb that has been extracted with a C1-C4 alcohol (methanol), as instantly claimed (see e.g. col 3, lines 43-44). Xu et al. disclose that such an extract comprises tannins including gamins A-F (see e.g. col 2, lines 36-40) and triterpenes including 2- α ,19- α -dihydroxy-3-oxo-12-ursen-28-oic acid, ursolic acid, epimolic acid, maslinic acid, euscaphic acid, tormenic acid, 28- β -D-glucoside of tormenic acid and (see e.g. col 3, lines 50- 67). Xu et al. also teach that 2-hydroxyoleanic acid and 2-hydroxyursolic acid are isolated *Geum Japonicum* Thunb (see e.g. col 2, lines 40-45) therefore they would be isolated during a methanolic extraction.

Therefore, the reference is deemed to anticipate the instant claims above.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1- 11 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xu et al.

A method for preparing an organic extract from Geum Japonicum Thunb is claimed. Dependent claims are drawn to the method wherein particular steps are performed for a certain amount of time and are repeated. Dependent claims are also drawn to the extraction wherein a particular chromatographic column (which has been specifically equilibrated with 10% by weight methanol) is used.

Xu et al. beneficially teach a method of extracting Geum Japonicum Thunb with methanol and is relied upon for the reasons set forth above. Xu et al. do not explicitly teach that the initial methanol extraction is performed for 2 hours and repeated 5 times. Xu et al. do, however, teach that the initial methanol extraction is performed 3 times (see e.g. col 8, lines 52-54). Adjustment of the extraction time is deemed judicious selection and optimization, and would have been obvious to and within the purview of the skilled artisan at the time the claimed invention was made. This is especially true in view of the fact that by performing the extraction method, Xu et al. obtained an extract comprising the same compounds as instantly claimed. Xu et al. also teach that a Sephadex LH-20 column is used (see e.g. col 13, lines 18-21). Xu et al. do not explicitly

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teach that the chromatographic column used is equilibrated with 10% by weight methanol.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to prepare a methanolic extract of *Geum Japonicum* Thunb in the manner instantly claimed. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the disclosure of Xu et al. that extracts containing with the particular compounds instantly claimed (i.e. tannins including gamins A-F (see e.g. col 2, lines 36-40) and triterpenes including 2- α ,19- α -dihydroxy-3-oxo-12-ursen-28-oic acid, ursolic acid, epimolic acid, maslinic acid, euscaphic acid, tormenic acid, 28- β -D-glucoside of tormenic acid and (see e.g. col 3, lines 50- 67) were obtained by performing the method steps as instantly claimed. The adjustment of particular conventional working conditions (e.g. the result-effective adjustment of the particular solvents and concentrations thereof used in chromatographic steps) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Claims 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiji et al. (JP 03190809).

A method for treating skeletal muscle injuries, skin injuries or bone fractures in an animal, comprising administration to the animal suffering from such conditions an effective amount of the extract of *Geum Japonicum* Thunb obtained by extracting *Geum*

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Japonicum Thunb in methanol is claimed. Dependent claims are drawn to the method wherein the animal is a mammal, in particular, a human.

Reiji et al. beneficially teach a skin medicine which comprises an extract of Geum Japonicum. Reiji et al. further teach that the extract is prepared using ethanol (C1-C4 alcohol). It is further disclosed by Reiji et al. that the extract is useful for improving chapped skin (a skin injury) (see e.g. English Abstract). The adjustment of particular conventional working conditions (e.g. providing the extract treatment to a particular animal) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to supply an alcoholic extract (including an ethanolic extract) to an individual suffering from chapped skin. One of ordinary skill in the art at the time the claimed invention was made would have been motivated and would have had a reasonable expectation of success in doing so based upon the beneficial teaching of Reiji et al. that such an extract is useful for improving chapped skin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion


No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melenie McCormick whose telephone number is (571) 272-8037. The examiner can normally be reached on M-F 7:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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PRIMARY EXAMINER